mft 28870

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esprix technologies



November 8, 2004

8EHQ-1104-15816

TSCA section 8 (e) Document Processing Center
D.P.C. (7407M) Attn: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
**U.S. Environmental Protection Agency**
1200 Pennsylvania Ave, NW
Washington, D.C. 20460

To Whom It May Concern:

On behalf of Esprix Technologies, I am reporting to the EPA (section 8(e) of TSCA ) that we have obtained information that a positive Ames Test has been performed in relation to the product named CR-5L (CAS# 68412-01-1).

*The Bacterial Reverse Mutation Assay performed by BioReliance Corporation 14920 Broschart Road Rockville, Maryland 20850; Study Number AA97ZB.501027.BTL – dated October 18, 2004 caused positive responses with tester strain TA98, TA100 and TA1535 in the presence of Aroclor-induced rat liver S9 activation and the tester strains TA100 and TA1535 without S9 activation.*

*According to tests done by our manufacturer of record Dainippon Ink and Chemicals, Incorporated, their Ames testing resulted in a positive result using salmonella typhimurium (strain TA100). This same test was not performed using other strains and Escherichia coli.*



By exercising good manufacturing practices, Esprix Technologies is in the process of notifying our customers and those that have received test samples of CR-5L over the past 36 months of this positive finding along with an update of our existing MSDS to reflect this positive Ames test result.

Any further information can be obtained by calling me at (941) 355-5100 ext 332.

Thank You.

Sincerely,

Linda Curhan 11/8/04

Linda Curhan

Regulatory Affairs

FINAL REPORT

Study Title

Bacterial Reverse Mutation Assay

Test Article

CR-5L

Sponsor Project Number

5280

Authors

Valentine O. Wagner, III, M.S.
Melissa R. VanDyke, B.S.

Study Completion Date

18 October 2004

Testing Facility

BioReliance
9630 Medical Center Drive
Rockville, MD 20850

BioReliance Study Number

AA97ZB.501027.BTL

Sponsor

Esprix Technologies
7680 Matoaka Road
Sarasota, FL 34243

**Bacterial Reverse Mutation Assay**

STUDY INFORMATION

| | |
|---|---|
| Sponsor: | **Esprix Technologies**<br>**7680 Matoaka Road**<br>**Sarasota, FL 34243** |
| Authorized Representative: | **Dana D. Field** |
| Testing Facility: | **BioReliance**<br>**9630 Medical Center Drive**<br>**Rockville, Maryland 20850** |
| Test Article I.D.: | **CR-5L** |
| Test Article Lot No.: | **M-173** |
| Sponsor Project No.: | **5280** |
| BioReliance Study No.: | **AA97ZB.501027.BTL** |
| Test Article Description: | **light yellow thick liquid** |
| Storage Conditions: | **room temperature in the dark** |
| Test Article Receipt and Login: | **17 August 2004 and 18 August 2004** |
| Study Initiation: | **25 August 2004** |
| Experimental Start Date: | **01 September 2004** |
| Experimental Completion Date: | **29 September 2004** |
| Laboratory Manager: | **Emily W. Dakoulas, B.S.** |
| Study Director: | Valentine O. Wagner, III 18 Oct 2004<br>Valentine O. Wagner, III, M.S. Date |

## EXPERIMENTAL DESIGN AND METHODOLOGY

### Test System

The tester strains used were the *Salmonella typhimurium* histidine auxotrophs TA98, TA100, TA1535 and TA1537 as described by Ames *et al.* (1975) and *Escherichia coli* WP2 *uvr*A as described by Green and Muriel (1976). Tester strains TA98 and TA1537 are reverted from auxotrophy to prototrophy by frameshift mutagens. Tester strain TA1535 is reverted by mutagens that cause basepair substitutions. Tester strain TA100 is reverted by mutagens that cause both frameshift and basepair substitution mutations. *E. coli* is reverted by mutagens that cause basepair substitutions.

### Experimental Design

The test system was exposed to the test article via the plate incorporation methodology originally described by Ames *et al.* (1975) and updated by Maron and Ames (1983). The test article was tested at five dose levels along with appropriate vehicle control and positive controls with overnight cultures of tester strains TA98, TA100, TA1535, TA1537 and WP2 *uvr*A on selective minimal agar in the presence and absence of Aroclor-induced rat liver S9. All dose levels of test article, vehicle control and positive controls were plated in duplicate.

### Plating and Scoring Procedures

Test article dilutions were prepared immediately before use and delivered to the test system at room temperature under yellow light. One-half (0.5) milliliter of S9 or Sham mix, 100 µL of tester strain and 50 µL of vehicle or test article dilution were added to 2.0 mL of molten selective top agar at 45±2°C. After vortexing, the mixture was overlaid onto the surface of 25 mL of minimal bottom agar. When plating the positive controls, the test article aliquot was replaced by a 50 µL aliquot of appropriate positive control. After the overlay had solidified, the plates were inverted and incubated for approximately 48 to 72 hours at 37±2°C. Plates that were not counted immediately following the incubation period were stored at 2-8°C until colony counting could be conducted.

The condition of the bacterial background lawn was evaluated for evidence of test article toxicity by using a dissecting microscope. Precipitate was evaluated by visual examination without magnification. Revertant colonies for a given tester strain and activation condition were counted either entirely by automated colony counter or entirely by hand unless the plate exhibited toxicity. Plates with sufficient test article precipitate to interfere with automated colony counting were counted manually.

### Evaluation of Results

For the test article to be evaluated positive, it must cause a dose-related increase in the mean revertants per plate of at least one tester strain over a minimum of two increasing concentrations

of test article. Data sets for tester strains TA1535 and TA1537 were judged positive if the increase in mean revertants at the peak of the dose response was equal to or greater than 3.0-times the mean vehicle control value. Data sets for tester strains TA98, TA100 and WP2 *uvr*A were judged positive if the increase in mean revertants at the peak of the dose response was equal to or greater than 2.0-times the mean vehicle control value.

**Criteria for a Valid Test**

The following criteria must be met for the mutagenicity assay to be considered valid. All *Salmonella* tester strain cultures must demonstrate the presence of the deep rough mutation (*rfa*) and the deletion in the *uvr*B gene. Cultures of tester strains TA98 and TA100 must demonstrate the presence of the pKM101 plasmid R-factor. All WP2 *uvr*A cultures must demonstrate the deletion in the *uvr*A gene. All cultures must demonstrate the characteristic mean number of spontaneous revertants in the vehicle controls as follows (inclusive): TA98, 10 - 50; TA100, 80 - 240; TA1535, 5 - 45; TA1537, 3 - 21; WP2 *uvr*A, 10 - 60. To ensure that appropriate numbers of bacteria are plated, tester strain culture titers must be greater than or equal to $0.3x10^9$ cells/mL. The mean of each positive control must exhibit at least a 3.0-fold increase in the number of revertants over the mean value of the respective vehicle control. A minimum of three non-toxic dose levels is required to evaluate assay data. A dose level is considered toxic if one or both of the following criteria are met: (1) A >50 % reduction in the mean number of revertants per plate as compared to the mean vehicle control value. This reduction must be accompanied by an abrupt dose-dependent drop in the revertant count. (2) At least a moderate reduction in the background lawn (background lawn code 3, 4 or 5). A copy of the Historical Negative and Positive Control Values is included in Appendix I.

**Archives**

Upon issue of the final report, all raw data for procedures performed at BioReliance will be returned to the Sponsor.

**Deviations**

No known deviations from the protocol or assay-method SOPs occurred during the conduct of this study.

## RESULTS AND DISCUSSION

### Solubility Test

A solubility test was conducted to select the vehicle. The test was conducted using water and dimethyl sulfoxide (DMSO). The test article was tested to determine the vehicle, selected in order of preference, that permitted preparation of the highest soluble or workable stock concentration, up to 50 mg/mL for aqueous solvents and 500 mg/mL for organic solvents. Dimethyl sulfoxide (DMSO) was selected as the solvent of choice based on solubility of the test article and compatibility with the target cells. The test article formed a soluble and clear solution in dimethyl sulfoxide (DMSO) at approximately 500 mg/mL, the highest concentration tested.

### Sterility Results

No contaminant colonies were observed on the sterility plates for the vehicle control, the test article dilutions and the S9 and Sham mixes.

### Mutagenicity Assay

The results of the mutagenicity assay are presented in Tables 1 through 10 and summarized in Tables 11 and 12. These data were generated in Experiments B1 and B2. The dose levels tested were 50, 150, 500, 1500 and 5000 µg per plate. Neither precipitate nor appreciable toxicity was observed.

In Experiment B1, positive responses were observed with tester strains TA98 (31.5-fold, maximum increase), TA100 (5.8-fold, maximum increase) and TA1535 (59.2-fold, maximum increase) in the presence of rat S9 activation and with tester strains TA100 (3.2-fold, maximum increase) and TA1535 (7.3-fold, maximum increase) in the absence of S9 activation. No other positive mutagenic responses were observed with the remaining test conditions. Due to unacceptable positive control values, tester strain TA98 in the absence of S9 activation was not evaluated but was retested in Experiment B2.

In Experiment B2 (Repeat Assay), no positive mutagenic responses were observed with tester strain TA98 in the absence of S9 activation.

## CONCLUSION

All criteria for a valid study were met as described in the protocol. The results of the **Bacterial Reverse Mutation Assay** indicate that, under the conditions of this study, test article **CR-5L** caused positive responses with tester strains TA98, TA100 and TA1535 in the presence of Aroclor-induced rat liver S9 activation and with tester strains TA100 and TA1535 in the absence of S9 activation.

## REFERENCES

Ames, B.N., J. McCann and E. Yamasaki (1975) Methods for Detecting Carcinogens and Mutagens with the *Salmonella*/Mammalian Microsome Mutagenicity Test, Mutation Research, 31:347-364.

Green, M.H.L. and W.J. Muriel (1976) Mutagen testing using trp+ reversion in *Escherichia coli*, Mutation Research 38:3-32.

Maron, D.M. and B.N. Ames (1983) Revised Methods for the *Salmonella* Mutagenicity Test, Mutation Research, 113:173-215.

Bacterial Mutation Assay

Table 1

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : TA98
Liver Microsomes : Rat liver S9
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL

Experiment No : B1
Cells Seeded : $3.3 \times 10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 17 | 1 | | |
| | 02 | 22 | 1 | 20 | 4 |
| 50 | 01 | 44 | 1 | | |
| | 02 | 28 | 1 | 36 | 11 |
| 150 | 01 | 64 | 1 | | |
| | 02 | 55 | 1 | 60 | 6 |
| 500 | 01 | 156 | 1 | | |
| | 02 | 151 | 1 | 154 | 4 |
| 1500 | 01 | 347 | 1 | | |
| | 02 | 272 | 1 | 310 | 53 |
| 5000 | 01 | 637 | 1 | | |
| | 02 | 621 | 1 | 629 | 11 |
| Positive Control 2-aminoanthracene 1.0 µg per plate | | | | | |
| | 01 | 157 | 1 | | |
| | 02 | 149 | 1 | 153 | 6 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 2

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : TA100
Liver Microsomes : None
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL

Experiment No : B1
Cells Seeded : 3.0 X $10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 183 | 1 | | |
| | 02 | 179 | 1 | 181 | 3 |
| 50 | 01 | 228 | 1 | | |
| | 02 | 173 | 1 | 201 | 39 |
| 150 | 01 | 217 | 1 | | |
| | 02 | 229 | 1 | 223 | 8 |
| 500 | 01 | 240 | 1 | | |
| | 02 | 241 | 1 | 241 | 1 |
| 1500 | 01 | 295 | 1 | | |
| | 02 | 293 | 1 | 294 | 1 |
| 5000 | 01 | 592 | 1 | | |
| | 02 | 561 | 1 | 577 | 22 |
| Positive Control sodium azide 1.0 µg per plate | | | | | |
| | 01 | 568 | 1 | | |
| | 02 | 562 | 1 | 565 | 4 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 3

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : TA100
Liver Microsomes : Rat liver S9
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL

Experiment No : B1
Cells Seeded : $3.0 \times 10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 196 | 1 | | |
| | 02 | 186 | 1 | 191 | 7 |
| 50 | 01 | 219 | 1 | | |
| | 02 | 241 | 1 | 230 | 16 |
| 150 | 01 | 249 | 1 | | |
| | 02 | 254 | 1 | 252 | 4 |
| 500 | 01 | 316 | 1 | | |
| | 02 | 348 | 1 | 332 | 23 |
| 1500 | 01 | 555 | 1 | | |
| | 02 | 497 | 1 | 526 | 41 |
| 5000 | 01 | 1066 | 1 | | |
| | 02 | 1139 | 1 | 1103 | 52 |
| Positive Control 2-aminoanthracene 1.0 µg per plate | | | | | |
| | 01 | 1339 | 1 | | |
| | 02 | 1129 | 1 | 1234 | 148 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 4

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : TA1535
Liver Microsomes : None
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL

Experiment No : B1
Cells Seeded : 5.2 X $10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 29 | 1 | | |
| | 02 | 23 | 1 | 26 | 4 |
| 50 | 01 | 23 | 1 | | |
| | 02 | 23 | 1 | 23 | 0 |
| 150 | 01 | 39 | 1 | | |
| | 02 | 34 | 1 | 37 | 4 |
| 500 | 01 | 37 | 1 | | |
| | 02 | 38 | 1 | 38 | 1 |
| 1500 | 01 | 91 | 1 | | |
| | 02 | 86 | 1 | 89 | 4 |
| 5000 | 01 | 189 | 1 | | |
| | 02 | 188 | 1 | 189 | 1 |
| Positive Control sodium azide 1.0 µg per plate | | | | | |
| | 01 | 421 | 1 | | |
| | 02 | 382 | 1 | 402 | 28 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 5

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : TA1535
Liver Microsomes : Rat liver S9
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL

Experiment No : B1
Cells Seeded : 5.2 X $10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 14 | 1 | | |
| | 02 | 17 | 1 | 16 | 2 |
| 50 | 01 | 35 | 1 | | |
| | 02 | 30 | 1 | 33 | 4 |
| 150 | 01 | 68 | 1 | | |
| | 02 | 55 | 1 | 62 | 9 |
| 500 | 01 | 137 | 1 | | |
| | 02 | 134 | 1 | 136 | 2 |
| 1500 | 01 | 403 | 1 | | |
| | 02 | 248 | 1 | 326 | 110 |
| 5000 | 01 | 987 | 1 | | |
| | 02 | 906 | 1 | 947 | 57 |
| Positive Control 2-aminoanthracene 1.0 µg per plate | | | | | |
| | 01 | 169 | 1 | | |
| | 02 | 152 | 1 | 161 | 12 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 6

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : TA1537
Liver Microsomes : None
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL

Experiment No : B1
Cells Seeded : 1.3 X $10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 11 | 1 | | |
| | 02 | 6 | 1 | 9 | 4 |
| 50 | 01 | 5 | 1 | | |
| | 02 | 11 | 1 | 8 | 4 |
| 150 | 01 | 12 | 1 | | |
| | 02 | 12 | 1 | 12 | 0 |
| 500 | 01 | 10 | 1 | | |
| | 02 | 5 | 1 | 8 | 4 |
| 1500 | 01 | 3 | 1 | | |
| | 02 | 6 | 1 | 5 | 2 |
| 5000 | 01 | 7 | 1 | | |
| | 02 | 4 | 1 | 6 | 2 |
| Positive Control 9-aminoacridine 75 µg per plate | | | | | |
| | 01 | 1059 | 1 | | |
| | 02 | 1043 | 1 | 1051 | 11 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 7

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : TA1537
Liver Microsomes : Rat liver S9
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL

Experiment No : B1
Cells Seeded : 1.3 X $10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 7 | 1 | | |
| | 02 | 5 | 1 | 6 | 1 |
| 50 | 01 | 8 | 1 | | |
| | 02 | 6 | 1 | 7 | 1 |
| 150 | 01 | 10 | 1 | | |
| | 02 | 8 | 1 | 9 | 1 |
| 500 | 01 | 7 | 1 | | |
| | 02 | 9 | 1 | 8 | 1 |
| 1500 | 01 | 9 | 1 | | |
| | 02 | 8 | 1 | 9 | 1 |
| 5000 | 01 | 12 | 1 | | |
| | 02 | 8 | 1 | 10 | 3 |
| Positive Control 2-aminoanthracene 1.0 µg per plate | | | | | |
| | 01 | 141 | 1 | | |
| | 02 | 113 | 1 | 127 | 20 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 8

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : WP2 *uvrA*
Liver Microsomes : None
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL

Experiment No : B1
Cells Seeded : $4.5 \times 10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 24 | 1 | | |
| | 02 | 17 | 1 | 21 | 5 |
| 50 | 01 | 17 | 1 | | |
| | 02 | 15 | 1 | 16 | 1 |
| 150 | 01 | 12 | 1 | | |
| | 02 | 16 | 1 | 14 | 3 |
| 500 | 01 | 18 | 1 | | |
| | 02 | 15 | 1 | 17 | 2 |
| 1500 | 01 | 12 | 1 | | |
| | 02 | 24 | 1 | 18 | 8 |
| 5000 | 01 | 15 | 1 | | |
| | 02 | 12 | 1 | 14 | 2 |
| Positive Control methyl methanesulfonate 1000 µg per plate | | | | | |
| | 01 | 96 | 1 | | |
| | 02 | 93 | 1 | 95 | 2 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 9

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : WP2 *uvrA*
Liver Microsomes : Rat liver S9
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL
Experiment No : B1
Cells Seeded : $4.5 \times 10^8$
Date Plated : 1 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 17 | 1 | | |
| | 02 | 19 | 1 | 18 | 1 |
| 50 | 01 | 11 | 1 | | |
| | 02 | 14 | 1 | 13 | 2 |
| 150 | 01 | 6 | 1 | | |
| | 02 | 15 | 1 | 11 | 6 |
| 500 | 01 | 9 | 1 | | |
| | 02 | 18 | 1 | 14 | 6 |
| 1500 | 01 | 15 | 1 | | |
| | 02 | 17 | 1 | 16 | 1 |
| 5000 | 01 | 32 | 1 | | |
| | 02 | 17 | 1 | 25 | 11 |
| Positive Control 2-aminoanthracene 10 µg per plate | | | | | |
| | 01 | 630 | 1 | | |
| | 02 | 425 | 1 | 528 | 145 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay

Table 10

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL
Strain : TA98
Liver Microsomes : None
Vehicle : dimethyl sulfoxide (DMSO)
Plating Aliquot : 50 µL
Experiment No : B2
Cells Seeded : 1.0 X $10^8$
Date Plated : 21 Sep 2004

| Concentration µg per plate | Plate Number | Revertants per plate | Background Code | Average Revertants | Standard Deviation |
|---|---|---|---|---|---|
| Vehicle | 01 | 21 | 1 | | |
| | 02 | 15 | 1 | 18 | 4 |
| 50 | 01 | 18 | 1 | | |
| | 02 | 9 | 1 | 14 | 6 |
| 150 | 01 | 14 | 1 | | |
| | 02 | 8 | 1 | 11 | 4 |
| 500 | 01 | 12 | 1 | | |
| | 02 | 18 | 1 | 15 | 4 |
| 1500 | 01 | 16 | 1 | | |
| | 02 | 15 | 1 | 16 | 1 |
| 5000 | 01 | 18 | 1 | | |
| | 02 | 13 | 1 | 16 | 4 |
| Positive Control 2-nitrofluorene 1.0 µg per plate | | | | | |
| | 01 | 178 | 1 | | |
| | 02 | 164 | 1 | 171 | 10 |

Background Lawn Code
1=Normal; 2=Slightly reduced; 3=Moderately reduced
4=Extremely reduced; 5=Absent; 6=Obscured by particulate
NP=Non-Interfering precipitate; IP=Interfering precipitate

Bacterial Mutation Assay
Summary of Results

Table 11

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL Experiment No : B1

Average Revertants Per Plate ± Standard Deviation

Liver Microsomes: None

| Dose (µg/plate) | TA100 | TA1535 | TA1537 | WP2 uvrA |
|---|---|---|---|---|
| Vehicle | 181 ± 3 | 26 ± 4 | 9 ± 4 | 21 ± 5 |
| 50 | 201 ± 39 | 23 ± 0 | 8 ± 4 | 16 ± 1 |
| 150 | 223 ± 8 | 37 ± 4 | 12 ± 0 | 14 ± 3 |
| 500 | 241 ± 1 | 38 ± 1 | 8 ± 4 | 17 ± 2 |
| 1500 | 294 ± 1 | 89 ± 4 | 5 ± 2 | 18 ± 8 |
| 5000 | 577 ± 22 | 189 ± 1 | 6 ± 2 | 14 ± 2 |
| Positive | 565 ± 4 | 402 ± 28 | 1051 ± 11 | 95 ± 2 |

Liver Microsomes: Rat liver S9

| Dose (µg/plate) | TA98 | TA100 | TA1535 | TA1537 | WP2 uvrA |
|---|---|---|---|---|---|
| Vehicle | 20 ± 4 | 191 ± 7 | 16 ± 2 | 6 ± 1 | 18 ± 1 |
| 50 | 36 ± 11 | 230 ± 16 | 33 ± 4 | 7 ± 1 | 13 ± 2 |
| 150 | 60 ± 6 | 252 ± 4 | 62 ± 9 | 9 ± 1 | 11 ± 6 |
| 500 | 154 ± 4 | 332 ± 23 | 136 ± 2 | 8 ± 1 | 14 ± 6 |
| 1500 | 310 ± 53 | 526 ± 41 | 326 ± 110 | 9 ± 1 | 16 ± 1 |
| 5000 | 629 ± 11 | 1103 ± 52 | 947 ± 57 | 10 ± 3 | 25 ± 11 |
| Positive | 153 ± 6 | 1234 ± 148 | 161 ± 12 | 127 ± 20 | 528 ± 145 |

Vehicle = Vehicle Control
Positive = Positive Control (50 µL plating aliquot)
Plating aliquot: 50 µL

Bacterial Mutation Assay
Summary of Results

Table 12

Test Article Id : CR-5L
Study Number : AA97ZB.501027.BTL Experiment No : B2

Average Revertants Per Plate ± Standard Deviation
Liver Microsomes: None

| Dose (µg/plate) | TA98 |
|---|---|
| Vehicle | 18 ± 4 |
| 50 | 14 ± 6 |
| 150 | 11 ± 4 |
| 500 | 15 ± 4 |
| 1500 | 16 ± 1 |
| 5000 | 16 ± 4 |
| Positive | 171 ± 10 |

Vehicle = Vehicle Control
Positive = Positive Control (50 µL plating aliquot)
Plating aliquot: 50 µL

## APPENDIX I

Historical Control Data

Historical Negative and Positive Control Values
2001 – 2003

revertants per plate

| Strain | Control | Activation | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | None | | | | Rat Liver | | | |
| | | Mean | SD | Min | Max | Mean | SD | Min | Max |
| TA98 | Neg | 15 | 5 | 5 | 49 | 20 | 7 | 5 | 49 |
| | Pos | 218 | 165 | 30 | 1981 | 695 | 385 | 40 | 2294 |
| TA100 | Neg | 159 | 34 | 76 | 262 | 167 | 36 | 80 | 271 |
| | Pos | 606 | 140 | 271 | 2373 | 956 | 438 | 262 | 2922 |
| TA1535 | Neg | 15 | 6 | 3 | 46 | 13 | 5 | 2 | 50 |
| | Pos | 344 | 140 | 16 | 1050 | 146 | 80 | 11 | 2246 |
| TA1537 | Neg | 7 | 3 | 1 | 23 | 7 | 3 | 1 | 28 |
| | Pos | 639 | 386 | 13 | 2351 | 131 | 135 | 12 | 2021 |
| WP2 *uvr*A | Neg | 14 | 4 | 5 | 58 | 14 | 4 | 4 | 46 |
| | Pos | 159 | 143 | 14 | 1809 | 447 | 277 | 22 | 1392 |

SD=standard deviation; Min=minimum value; Max=maximum value; Neg=negative control (including but not limited to deionized water, dimethyl sulfoxide, ethanol and acetone); Pos=positive control

Technical Information

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# Crosslinking Agent for Polyurethene Ionomers

# CR-5L

## DESCRIPTIONS

CR-5L is a water soluble and multifunctional aliphatic epoxide.
CR-5L is useful for a crosslinking agent for various type of emulsions and dispersion and improves various durability, for examples, excellent fastness to heat ,water , and solvent.

## APPLICATIONS

Crosslinking agent for polyurethane ionomers or other emulsions.

## TYPICAL PROPERTIES

| | |
|---|---|
| Appearance | :yellow viscous liquid |
| Non volatiles(%) | :100 |
| Viscosity(mPa.s) | :2000-10000 |
| Weight per epoxy equivalent | :appro.180 |

## NOTE

1)after use, the container should be tightly closed.
2)Use adequate protective gloves, goggles, and ventilation in handling.
3)Flammable

READ THE MATERIAL SAFETY DATA SHEET BEFORE HANDLING, STORING OR USING THIS PRODUCT.

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# Material Safety Data Sheet

Date Prepared: 8/7/2001 Date Revised: 07/08/2004

## 1. Identification

| | |
|---|---|
| Chemical Name: | Epoxy Resin |
| Trade Name: | CR-5L |
| CAS Number: | 68412-01-1 |
| Molecular Formula: | $C_6H_{14}O_6$*$C_3H_5ClO$ |
| TSCA Inventory: | Listed |

## 2. Composition

| | |
|---|---|
| Substance: | Epoxy Resin (Polyhydroxyalcan Polyglycidylether Mixture) |
| % Content: | 100% |
| CAS Number: | 68412-01-1 |

## 3. Hazards Identification

**Physical Appearance and Odor:** Yellowish viscous liquid with a glycolic odor

**Warning Statements:**

| | |
|---|---|
| **Health:** | Moderately skin irritation. Ames test using salmonella typhimurium (strain TA-100) was positive but same test was not investigated with using other strains and Escherichia coli. |
| **Flammability:** | Weak |
| **Chemical Reactivity:** | Stable |

The toxicological properties of this material have not been fully investigated. Use appropriate procedures to prevent opportunities for direct contact with the skin or eyes and to prevent inhalation.

## 4. First Aid Measures

**Eye Contact:**
Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes. Seek medical attention if irritation develops or persists or if visual changes occur.

**Skin Contact:**
Immediately wash with plenty of soap and water for at least 15 minutes. Seek medical attention if irritation develops or persists. Remove contaminated clothing and shoes. Clean contaminated clothing or shoes before re-use.

**Ingestion:**
If victim is conscious and alert, give large quantity of water to drink. **Do Not Induce Vomiting.** Never induce vomiting or give anything by mouth to an unconscious person. Seek immediate medical attention. Do not leave victim unattended. Vomiting may occur spontaneously. To prevent aspiration of swallowed

product, lay victim on side with head lower than waist. If vomiting occurs and the victim is conscious, give water to further dilute chemical.

**Inhalation:**
If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, seek medical attention. Do not leave victim unattended.

## 5. Fire Fighting Measures

**Flash Point:** >212°C

**Extinguishing Media:** Dry chemical, chemical foam, or carbon dioxide.

**Special Firefighting Procedures:**
Firefighters should wear NIOSH/MSHA approved self-contained breathing apparatus and full protective clothing. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

**Unusual Fire and Explosion Hazards:** Emits toxic fumes under fire conditions.

**Hazardous Decomposition Materials (Under Fire Conditions):**
Carbon monoxide and carbon dioxide.

## 6. Accidental Release Measures

**Personal Precautions:**
Wear appropriate protective gear for situation (See Section 8).

**For Spill:**
Absorb spill with inert material such as sand or vermiculite. Place in suitable container and hold for proper disposal. Ventilate and wash spill site after material pickup is complete. Avoid runoff into storm sewers and ditches which lead to waterways.

## 7. Handling and Storage

**Handling:**
Avoid breathing mist or vapor, work in well ventilated area. Avoid prolonged and repeated exposure. Avoid direct or prolonged contact with skin and eyes. Avoid ingestion or inhalation. Use only in a well-ventilated area. Wash thoroughly after handling.

**Storage:**
Store in tightly closed containers. Store in an area that is cool and dry, temperatures between 5 and 35°C. The product tends to settle during storage. Therefore please agitate thoroughly before using. Keep away from heat, sparks, and flame. Keep away from strong acids, bases and certain metallic salts.

## 8. Exposure Controls/Personal Protection

**Introductory Remarks:**
These recommendations provide general guidelines for handling of this product. Because specific work environments and material handling practices vary, safety procedures should be developed for each intended application. While developing safe handling procedures, do not overlook the need to clean equipment and piping systems for maintenance and repairs. Waste resulting from these procedures should be handled in accordance with section 13.

**Respiratory Protection:**
When respirators are required, select NIOSH/MSHA approved equipment based on actual or potential airborne concentrations and in accordance with the appropriate regulatory standards and/or industrial recommendations.

Under normal conditions, in the absence of other airborne contaminates, the following devices should provide protection from the material up to the conditions specified by the appropriate OSHA standard(s): Air-purifying (half mask/full face) respirator with cartridges/canister approved for use against dusts, mists, and fumes.

**Eye/Face Protection:**
Eye and face protection requirements will vary upon work environment conditions and material handling practices. Appropriate ANSI Z87 approved equipment should be selected for the particular use intended for this material.

It is generally regarded as good practice to wear a minimum of safety goggles with side shields when working in industrial environments.

**Skin Protection:**
Skin contact should be minimized through the use of chemical resistant gloves and suitable long-sleeved clothing.

**Work Practice Controls:**
Personal hygiene is an important work practice exposure control measure and the following general measures should be taken when handling this material:

(1) Do not store, use, and/or consume foods, beverages, tobacco products, or cosmetics in areas where this material is stored.
(2) Wash hands and face carefully before eating drinking, using tobacco, applying cosmetics, or using the toilet.
(3) Wash exposed skin promptly to remove accidental splashes of contact with this material.
(4) Ventilation is normally required when handling or using this product to keep exposure to airborne contaminants below the exposure limits.
(5) Safety shower and emergency eyewash station should be made readily accessible when working with this product.

## 9. Physical and Chemical Properties

Physical and chemical properties here represent typical properties of this product. Contact the business area using the Product Information phone number on page 1 for its exact specifications.

| | |
|---|---|
| Appearance: | Yellowish viscous liquid |
| Odor: | Glycolic odor |
| Freezing point: | NA |
| Boiling point: | NA |
| Flashpoint: | 212°C (open cup method) |
| Volatiles: | NA |
| Solubility: | Partially soluble in water |
| Relative Density: | 1.26 g/mL @ 25°C |

## 10. Stability and Reactivity

| | |
|---|---|
| **Chemical Stability:** | Stable under ambient temperatures. |
| **Conditions to Avoid:** | Prevent the product from freezing. Store indoors in between 5 and 35°C. |
| **Materials to Avoid:** | Material can react with strong acids and bases, and oxidizing agents, epoxy hardeners. |

**Polymerization to Avoid:** No information available.
**Hazardous Decomposition Products:** Carbon Monoxide and Carbon Dioxide.

## 11. Toxicological Information

**Inhalation:** No data
**Skin:** Primary Irritation Index 0.5 (mildly irritating)
**Ingestion:** The oral $LD_{50}$ for rats is 5.1 g/kg (slightly toxic).
**Mutagenicity:** Ames test using salmonella typhimurium (strain TA-100) was positive but the same test was not investigated with using other strains and Escherichia coli.
**October 18, 2004**: Results of the Bacterial Reverse Mutation Assay (Ames Test) caused positive responses with tester strains TA98, TA100 and TA1535 in the presence of Aroclor-induced rat liver S9 activation and with tester strains TA100 and TA1535 in the absence of S9 activation.

## 12. Ecological Information

No information available. Do not allow runoff into sewers or waterways.

## 13. Disposal Considerations

Chemical additions, processing or otherwise altering this material may make the waste management information presented in this MSDS incomplete, inaccurate, or otherwise inappropriate. Please be advised that state and local requirements for waste disposal may be more restrictive or otherwise different from federal laws and regulations. Consult state and local regulations regarding proper disposal of this material.

## 14. Transport Information

**US Department of Transportation**

| | |
|---|---|
| Hazard Class: | Not Applicable |
| DOT Shipping Name: | Non-Regulated Chemical, n.o.s. |
| UN Number: | Not Applicable |
| Packing Group: | Not Applicable |

**Other information:** Avoid temperature below 0°C. Keep separated from foodstuffs.

## 15. Regulatory Information

**FEDERAL REGULATIONS**

**Inventory Issues:** This product is listed on the TSCA Inventory.

**EINECS:** This product is listed on EINECS.

Ensure this material is in compliance with federal requirements and ensure conformity to local regulations in your country.

## 16. Other Information

**Disclaimer**

The information contained herein is based on our experience and technical data. Considering there are many factors beyond our knowledge and control, we cannot accept liability for any loss, injury, or damage resulting from reliance upon such information.

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